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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

HM12/0428

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ART UNIT	PAPER NUMBER
1648	8

DATE MAILED: 04/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7 and 24-25, drawn to methods of treating HIV infection, classified in Class 424, subclass 208.1.

II. Claims 8-14, drawn to HIV env preparations and vaccines, classified in Class 424, subclass 208.1 and 530, subclass 395.

III. Claims 15-16, drawn to methods of producing HIV proteins, classified in Class 530, subclass 413.

IV. Claims 17-18, drawn to recombinant DNA methods for making HIV proteins, classified in Class 435, subclass 69.1.

V. Claims 19-23, drawn to monoclonal antibodies specific for HIV env, compositions and method of use, classified in Class 424, subclass 148.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the HIV env preparations could be used for immunoaffinity purification of anti-HIV antibodies.

Inventions (III and IV) and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)). In the instant case the product could be made by either immunoaffinity purification or by recombinant DNA methods.

Further, the products of Groups II and V differ one from another in their physical properties such as chemical structure, primary sequence and molecular weight and are novel and unobvious in view of each other. Therefore, the inventions of Groups II and V are patentably distinct.

Further, the methods of Groups I, III and IV each differ one from another in method steps, reagents, and utility and are novel and unobvious in view of each other. Therefore, the inventions of Groups I, III and IV are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

Should Applicants elect Group V, the following election of species is required.

Claims 19-23 are generic to a plurality of disclosed patentably distinct species comprising monoclonal antibodies to HIV env proteins as listed in claims 19-21. These species are directed to monoclonal antibodies having different properties such as specificity and affinity for HIV and are novel and unobvious in view of each other and, therefore, are patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species from the antibodies listed in claims 19-21, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

A telephone call was made to Mr. Timothy Torchia, on September 9, 1998, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. (37 C.F.R. 1.143).

PLEASE NOTE: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or (703) 308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Don Adams, can be reached at (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.

Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
September 10, 1998